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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,853

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Yung-Nien Chang

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EXAMINER

LONG, SCOTT

ART UNIT

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1633

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/602,853	<b>Applicant(s)</b> CHANG ET AL.	
	<b>Examiner</b> SCOTT LONG	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7/18/2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

*The examiner acknowledges receipt of Applicant's Remarks and Claim Amendments and Specification amendments, filed 18 July 2008.*

#### ***Claim Status***

Claims 38-96 are pending. Claims 38, 40, 51, 54, and 63 have been amended. Claims 38-96 are under current examination.

#### ***Priority***

This application claims benefit as a DIV of 08/974,391 (filed 11/19/1997; issued as US PAT 6,638,762) which is a CIP of 08/487,992 (filed 06/07/1995 ABN) which is a CIP of 08/348,258 (filed 11/28/1994 ABN) and said 08/974,391 (filed 11/19/1997) which is a CIP of 08/849,117 (filed 08/01/1997; issued as US PAT 5,998,205) which is a 371 of PCT/US95/15455 (filed 11/28/1995) which is a CIP of 08/487,992 (filed 06/07/1995 ABN) which is a CIP of 08/348,258 (filed 11/28/1994 ABN).

Therefore, the instant application has been granted the benefit date, 28 November 1994, from the application 08/348258 (abandoned).

#### ***Specification***

The examiner acknowledges receipt of the amendments to the specification. There is no new matter introduced by the amendments to the specification.

***RESPONSE TO ARGUMENTS***

***Claim Rejections - 35 USC § 112***

The rejection of claims 38-96 under 35 U.S.C. 112, first paragraph (scope of enablement), is withdrawn in response to the applicant's arguments and/or amendments.

Applicant's arguments (Remarks, pages 12-14) have been fully considered and are persuasive. The applicant has amended the instant claims to remove certain promoters identified as being tissue specific, namely thymidine kinase, p21 and cyclin. In addition, the applicant has submitted references which have demonstrated that the art recognizes MUC1/DF3 promoter as being tissue specific (see Gupta et al. *Gene Therapy* 2003; 10:206-212 and Kurihara et al. *J.Clin.Invest.* 2000; 106:763-771). The examiner finds these references sufficient to overcome the examiner's assertion that MUC1/DF3 promoter is not a tissue specific promoter.

Accordingly, the examiner hereby withdraws the rejection of claims 38-96 under 35 U.S.C. 112, first paragraph (scope of enablement).

***Claim Rejections - 35 USC § 103***

The rejections of claims 38-96 under 35 U.S.C. 103(a) is withdrawn in response to the applicant's arguments and/or amendments.

Applicant's arguments (Remarks, pages 15-18) have been fully considered and are persuasive. The applicant has argued that the base reference for the several 35

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USC 103 rejections is not properly considered prior art. The examiner was mistaken in applying the Henderson et al (US Patent 5,698,443) reference as prior art. The priority date for Henderson is after the priority date of the instant application. Therefore, the 35 USC 103 rejections from the prior Action (2/21/2008) were improper.

Accordingly, the examiner hereby withdraws the rejection of claims 38-96 under 35 U.S.C. 103(a) as being obvious over Henderson et al (US-5,698,443) in view of secondary references (Woo or Britchard or Abe or Smith).

### ***Claim Rejections – Obviousness Double Patenting***

The rejections of claims 38-96 for provisional obviousness double patenting over claims 19-23, 26-34 and 36-40 of US Application 11/601,071 remain rejected for the reasons of record and the comments below.

Applicant's arguments (Remarks, page 18) have been fully considered but are unpersuasive. The applicant has argued that the base reference for the several 35 USC 103 rejections is not properly considered prior art. The examiner was mistaken in applying the Henderson et al (US Patent 5,698,443) reference as prior art. The priority date for Henderson is after the priority date of the instant application. Therefore, the 35 USC 103 rejections from the prior Action (filed 2/21/2008) were improper.

Accordingly, the examiner hereby maintains the rejection of claims 38-96 under 35 U.S.C. 103(a) as being obvious over Henderson et al (US-5,698,443) in view of secondary references (Woo or Britchard or Abe or Smith).

## ***NEW GROUNDS OF REJECTION***

### ***Provisional Rejection, Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38-96 are provisionally rejected on the ground of nonstatutory double patenting over claims 19 of copending Application No. 11/977902. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

A tissue-specific replication-conditional adenovirus vector comprising a heterologous tissue-specific transcriptional regulatory sequence operably linked to the coding region of a gene that is essential for replication of said vector, an isolated cell containing a tissue-specific conditional replication vector and a method for producing said virion.

Because claims 38-96 of the instant application are drawn broadly to a cell containing a tissue tissue-specific replication-conditional vector comprising at least a tissue specific transcriptional regulatory sequenced operably linked to the coding region of a gene that is essential for replication of said vector, claims 19-23, 26-34 and 36-40 of the instant application embrace the invention as set forth in claims 19 of copending Application No. 11/977902.

Claims 38-96 are provisionally rejected on the ground of nonstatutory double patenting over claims 1 and 41-75 of copending Application No. 11/977533. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

A tissue-specific replication-conditional adenovirus vector comprising a heterologous tissue-specific transcriptional regulatory sequence operably linked to the coding region of a gene that is essential for replication of said vector, an isolated cell containing a tissue-specific conditional replication vector and a method for producing said virion.

Because claims 38-96 of the instant application are drawn broadly to a cell containing a tissue tissue-specific replication-conditional vector comprising at least a tissue specific transcriptional regulatory sequenced operably linked to the coding region of a gene that is essential for replication of said vector, claims 38-96 of the instant application embrace the invention as set forth in claims 1 and 41-75 of copending Application No. 11/977533.



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Claims 38-96 are rejected on the ground of nonstatutory double patenting over claims 1-87 of US Patent 6,551,687. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

A tissue-specific replication-conditional adenovirus vector comprising a heterologous tissue-specific transcriptional regulatory sequence operably linked to the coding region of a gene that is essential for replication of said vector, an isolated cell containing a tissue-specific conditional replication vector and a method for producing said virion.

Because claims 38-96 of the instant application are drawn broadly to a cell containing a tissue tissue-specific replication-conditional vector comprising at least a tissue specific transcriptional regulatory sequenced operably linked to the coding region of a gene that is essential for replication of said vector, claims 38-96 of the instant application embrace the invention as set forth in claims 1-87 of US Patent 6,551,687.

Claims 38-96 are rejected on the ground of nonstatutory double patenting over claims 1-59 of US Patent 6,638,762. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

A tissue-specific replication-conditional adenovirus vector comprising a heterologous tissue-specific transcriptional regulatory sequence operably linked to the coding region of a gene that is essential for replication of said vector, an isolated cell

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containing a tissue-specific conditional replication vector and a method for producing said virion.

Because claims 38-96 of the instant application are drawn broadly to a cell containing a tissue tissue-specific replication-conditional vector comprising at least a tissue specific transcriptional regulatory sequenced operably linked to the coding region of a gene that is essential for replication of said vector, claims 38-96 of the instant application embrace the invention as set forth in claims 1-59 of US Patent 6,638,762.

Claims 38-96 are rejected on the ground of nonstatutory double patenting over claims 1-20 of US Patent 5,998,205. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

A tissue-specific replication-conditional adenovirus vector comprising a heterologous tissue-specific transcriptional regulatory sequence operably linked to the coding region of a gene that is essential for replication of said vector, an isolated cell containing a tissue-specific conditional replication vector and a method for producing said virion.

Because claims 38-96 of the instant application are drawn broadly to a cell containing a tissue tissue-specific replication-conditional vector comprising at least a tissue specific transcriptional regulatory sequenced operably linked to the coding region

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of a gene that is essential for replication of said vector, claims 38-96 of the instant application embrace the invention as set forth in claims 1-20 of US Patent 5,998,205.

***Conclusion***

No claims are allowed.

***Examiner Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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